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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,946	04/19/2001	L. David Williams	MVIEWD.1A2DV1	5256

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EXAMINER	
SAIDHA, TEKCHAND	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,946	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-59 and 74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-56,58,59 and 74-76* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Applicants' papers filed on 07.06.2004 for a Request for Continued Prosecution (RCE) under 37 CFR 1.114 based on parent Application No. 09/839,946 is acceptable and a RCE has been established. An action on the RCE follows.

2. Applicant's arguments filed 07.06.2004 have been considered and not found to be persuasive for reasons of record. The following references are cited for record only and have not been used any prior art rejections. These references do not have much relevance to the claims as amended, because the claims do not any more recite '10% non-tetrameric uricase aggregates'. These references are cited to show the "inverse relationship between the protein concentration and aggregation". The arguments presented previously were and are therefore the basis of a sound scientific reasoning. These references are (1) Ishino et al. Agricultural and Biological Chemistry (1980), 44(6), 1259-66, (2) Treuheit et al. Pharmaceutical research, (2002 Apr) 19 (4) 511-6, and (3) Herbst et al. Biochemistry, (1998 May 5) 37 (18) 6586-97.

3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

4. Claims 50-59 & 74-76 drawn to an isolated tetrameric mammalian uricase are pending and under consideration in this Office Action.

5. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al. [Science 239, 1288-1291 (1988), IDS, previously cited].

Lee et al. (1988) teach the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 daltons (page 1288, column 2,first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate oxidase (see, page 1289, second column). Oxidation of uric acid to allantoin is catalyzed by urate oxidase (see abstract). Increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis (page 1288, column 2).

Applicants' claims are directed to 'tetrameric mammalian uricase, wherein at least about 90% is in tetrameric form'. This is interpreted here to mean that more than 90% may also be present in the tetrameric form. More than 90% may also mean 100% or homogenous preparation. Therefore, the homogenous preparations of porcine or murine tetrameric uricase comprises the at least about

90% tetrameric form of mammalian uricase claimed. The reference therefore anticipates the claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. as applied to claims 50-51 above, and further in view of Caput et al. [USP 5,382,518, January 17, 1995].

The teachings of Lee et al. are described above. Lee et al. do not teach a pharmaceutical composition for lowering uric acid levels, but teach that increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis.

Caput et al. teach purification of Urate oxidase from *Aspergillus*, an enzyme which catalyzes the degradation of uric acid to allantoin (a compound which is much more soluble than uric acid and does not crystallize at the concentrations reached in biological fluids), and therefore has therapeutic value. Pharmaceutical compositions (see column 1-2, claim 7, and the entire patent) for lowering the uric acid levels as a means for treatment of conditions associated with increased uric acid are also taught. Caput et al. do not teach mammalian uricase.

It would have been obvious for one of ordinary skill in the art to substitute Aspergillus uricase of Caput et al. with the mammalian uricase taught by Lee et

al. in developing pharmaceutical compositions for lowering uric acid in body fluid of man and do so with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so in view of the knowledge that man belongs to the class of mammals and a uricase originating from a mammalian species will be more compatible and perhaps more effective in lowering uric acid in man.

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 50-56, 58-59 & 74-76 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 09/501,730 (allowed). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

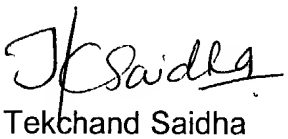
8. Claim 57 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone

number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



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